

WHAT IS CLAIMED IS:

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1. An apparatus for delivering a prosthesis into a blood vessel of a patient, comprising:

an elongate tubular member having (a) proximal end, a distal  
5 end, and a lumen extending between the proximal and distal ends, the distal end having a size for endoluminal insertion into a blood vessel and terminating in a substantially atraumatic distal portion comprising a plurality of flexible leaflets integrally molded thereto, the leaflets being deflectable from a closed  
10 position wherein the leaflets engage one another to an open position wherein the leaflets define an opening communicating with the lumen;

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a tubular prosthesis disposed within the lumen proximate the distal portion; and

15 an elongate bumper member having a proximal end and a distal end, the bumper member being slidably disposed within the lumen of the sheath, the distal <sup>of the bumper member</sup> end having a blunt edge disposed adjacent <sup>the</sup> (a) proximal end of the prosthesis for preventing axial  
20 displacement of the prosthesis upon retraction of the tubular member with respect to the bumper member.

2. The apparatus of claim 1, wherein the prosthesis comprises a self-expanding stent, the stent being biased to assume an expanded condition having a cross-section larger than the lumen of the tubular member, and being compressible to a contracted condition to facilitate insertion into the lumen.

3. The apparatus of claim 1, wherein the leaflets define a substantially rounded bullet shape in the closed position.

4. The apparatus of claim 1, wherein the leaflets define a substantially conical shape in the closed position.

5. The apparatus of claim 1, wherein the leaflets are substantially flexible and independently deflectable at a temperature less than body temperature.

6. The apparatus of claim 1, wherein the leaflets are biased towards the closed position, but are resiliently deflectable to the open position.

7. The apparatus of claim 1, wherein adjacent leaflets are connected to one another by weakened regions, the weakened regions being tearable upon retraction of the tubular member with respect to the prosthesis to allow the leaflets to be deflected  
5 towards the open position.

8. The apparatus of claim 1, wherein adjacent leaflets are separated by a slit such that the leaflets are independently deflectable.

9. The apparatus of claim 1, wherein the leaflets include a portion having a thickness that is substantially thinner than a wall thickness of the distal portion of the sheath from which the leaflets extend.

10. The apparatus of claim 1, wherein the bumper member comprises a helical coil.

11. An apparatus for delivering a prosthesis into a blood  
20 vessel of a patient, comprising:

an elongate tubular member having a proximal end, a distal end, and a lumen extending between the proximal and distal ends, the distal end having a size for endoluminal insertion into a blood vessel;

5 a tubular prosthesis disposed within the lumen proximate the distal end; and

an elongate bumper member comprising a helical coil having a proximal end and a distal end, the bumper member being slidably disposed within the lumen of the sheath, the distal end having a blunt distal edge disposed adjacent a proximal end of the prosthesis for preventing axial displacement of the prosthesis upon retraction of the tubular member with respect to the bumper member.

15 12. The apparatus of claim 11, wherein the tubular member comprises a substantially atraumatic distal portion comprising a plurality of flexible leaflets integrally molded thereto, the leaflets being deflectable from a closed position wherein the leaflets engage one another to an open position wherein the  
20 leaflets define an opening communicating with the lumen.

13. The apparatus of claim 12, wherein the leaflets define  
a substantially rounded bullet shape in the closed position.

14. The apparatus of claim 12, wherein the leaflets are  
5 substantially flexible and independently deflectable at a  
temperature less than body temperature.

15. The apparatus of claim 12, wherein the leaflets are  
biased towards the closed position, but are resiliently  
10 deflectable to the open position.

16. The apparatus of claim 11, wherein the bumper member  
comprises a helical wire compression coil extending between its  
proximal and distal ends.

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17. The apparatus of claim 11, wherein the bumper member  
comprises a plastic bumper element extending from a distal end of  
the helical coil, the bumper element including the blunt distal  
edge thereon.

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18. The apparatus of claim 17, wherein the bumper member  
further comprises an extension element extending from the bumper  
element, the extension element having a cross-section  
substantially smaller than the bumper element, whereby the  
5 extension element may extend through the prosthesis disposed  
within the lumen of the tubular member.

19. The apparatus of claim 18, wherein the extension  
element comprises a lumen for receiving a guidewire therethrough.

20. The apparatus of claim 11, further comprising a  
radiopaque marker on the distal end of the bumper member.

21. A method for making a sheath for delivering a treatment  
15 element within a body lumen of a patient, the method comprising:  
providing a tubular member formed from a substantially  
flexible material, the tubular member having a proximal end, a  
distal end, and a lumen extending axially between the proximal  
and distal ends, the distal end having a size for endoluminal  
20 insertion into a body lumen;

providing a die having a bore therein, the bore having a tapered shape;

heating the die to a temperature in excess of a melting point of the flexible material from which the tubular member is formed;

inserting the distal end of the tubular member into the bore of the heated die until a distal portion of the tubular member is softened and deformed into a tapered shape substantially enclosing the distal end;

creating one or more slits in the distal portion of the tubular member after it is deformed into the tapered shape, the slits defining a plurality of leaflets; and

inserting a treatment element into the lumen of the tubular member until it is disposed proximate the distal portion.

22. The method of claim 21, further comprising inserting a bullet having a tapered-shaped distal end into the distal end of the tubular member before inserting the distal end of the tubular member into the bore.

23. The method of claim 22, wherein the bullet and the bore have corresponding substantially rounded shapes defining a mold cavity therebetween when the distal end of the tubular member is inserted into the bore.

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24. The method of claim 21, wherein the treatment element comprises a tubular prosthesis for implantation within a body lumen of a patient.

25. The method of claim 24, further comprising inserting an elongate bumper member into the lumen of the tubular member, the bumper member being slidably disposed within the lumen of the tubular member, the distal end having a blunt distal edge for abutting a proximal end of the prosthesis.

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26. The method of claim 25, further comprising:

providing an elongate helical coil having a proximal end and a distal end; and

attaching a tubular bumper element to the distal end of the helical coil to provide the bumper member, the bumper element comprising the blunt distal edge of the bumper element.



27. The method of claim 26, further comprising attaching a tubular extension element to the bumper element, the extension element having a cross-section substantially smaller than the bumper element.

28. The method of claim 26, wherein the bumper element comprises plastic, and wherein the step of attaching the bumper element to the helical coil comprises:

heating the bumper element until it is softened; and  
directing the softened bumper element over the distal end of the helical coil.

29. The method of claim 24, wherein the prosthesis comprises a self-expanding stent biased to assume an expanded condition having a cross-section larger than the lumen, and compressible to a contracted condition before being inserted into the lumen of the tubular member.

30. The method of claim 24, wherein the prosthesis is inserted into the lumen of the tubular member before inserting the distal end of the tubular member into the bore.

5 31. The method of claim 24, wherein the prosthesis is inserted into the lumen from the distal end of the tubular member.

32. The method of claim 24, wherein the prosthesis is inserted into the lumen from the proximal end of the tubular member.

33. The method of claim 21, wherein the step of creating one or more slits comprises cutting a plurality of slits in the tapered shape distal portion, the slits extending substantially radially from an apex of the tapered shape distal portion.

34. The method of claim 21, wherein the slits extend only partially through a wall of the tapered shape distal portion, thereby defining weakened regions between the leaflets.

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of claim 35, wherein t  
substantially enclosin  
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opening communicating

5           36. The method of claim 35, wherein the leaflets are biased to a closed position substantially enclosing the lumen of the tubular member, and are resiliently deformable to an open position defining an opening communicating with the lumen of the tubular member.

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